UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,197	01/12/2001	Pedro Aloise	BIO76701	2671

7590 01/27/2003

John Russell Uren, P. Eng.
Suite 202
1590 Bellevue Avenue
West Vancouver, BC V7V 1A7
CANADA

EXAMINER	
SAYALA, CHHAYA D	
ART UNIT	PAPER NUMBER
1761	8

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-8

Office Action Summary

Application No.	Applicant(s)
09/760197	Pedro et al
Examiner	**Group Art Unit**
Seyale	1761

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☑ Responsive to communication(s) filed on 11/8/02.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-15 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

---

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, line 3, "other" is indefinite because, it is not clear what else is included by this language.

Claim 15 is improper and indefinite in that it is unclear which method and which claim is being referred to since a number of the claims 1-14 encompass several Markush groups.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/34498 and Stone et.al. (J. Sci. Food Agric. Vol 35, pp 513-519, 1984) in view of EP 0321004 and Nielsen et al. (US Patent 5989600).

'498 teaches mixing krill hydrolysate with soy, canola and other plant protein along with wheat bran, being brought to a desired temperature of about 45°C, and holding it for about 1 hour at this temperature. The phytic acid and levels of acid and base are measured. Wheat bran is used to provide phytase. The patent teaches that the blend can be maintained to an extended period of time, 4 hours or even longer. The krill hydrolysate product is evaporated and then mixed with and co-dried with a dry carrier, such as canola meal, oil seed meal, which renders obvious the soybean meal and other vegetable meals. The advantages are given at p. 20; see page 19 and page 22, lines 5-10.

'498 also teaches using formic acid to stabilize the hydrolyzed marine protein. It does not teach adding acid to stabilize hydrolyzed feed materials from vegetable/oil seed protein. However, it would have been obvious to use the same acid to stabilize such since the krill hydrolysate used is the same.

The patent does not teach the use of a phytase enzyme instead of wheat bran, and does not teach the use of a pH between 5-5.5.

Stone et. al teach acid-stabilized blend of fish silage, wheat bran and canola meal to make a feed-stuff. The pH is maintained at 4.0 and the final blend is dried. Stone et al. teach stabilizing the product with acid at page 518, second paragraph.

The use of phytase enzyme is not taught and neither is the pH the same as claimed herein.

EP 0321004 teaches the uses of phytase either from wheat or from microbial source. It also teaches using a combination of enzymes that possess plant degrading properties. See claims 1-4. See claim 6, wherein the process teaches drying the hydrolyzed product.

Nielsen et al. also teach using a combination of enzymes such as phytase and proteolytic enzymes for dephosphorylating the same cereals, see col. 1, lines 53-55; col. 3, lines 40-65. The pH used is between 4-7. The temperatures are from 35-65°C. See col. 3, lines 10-25.

It would have been obvious to combine krill hydrolyzate, canola meal, phytase or other film-degrading enzymes used in EP '004 or Nielsen et. al., to prepare a feedstuff as taught by WO '498 and drying the hydrolyzed product as shown in the secondary reference and co-drying with other feed ingredients as shown by

---

'498. Note that all patents are drawn to hydrolyzing feed materials to make animal feedstuff by using phytase enzyme. To substitute the wheat bran of the primary references (Stone et.al, WO '498) with phytase would have been an obvious substitution since these references teach that wheat bran is used as a phytase source and both Nielsen et. al. and EP'498 use the phytase enzyme itself The temperatures shown by these references are close to or encompass these parameters claimed herein and to optimize such, based on the known phytase activity around pH 5 to 5.5 would have been an obvious expedient.

6. Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO98/34498, or Stone et.al., or EP 0286056, or Vanderbeke et. al. (US Patent 5554399) or Nielsen et. al (US Patent 5989600) or WO 00/10404 or EP 0321004.

The patents/references above teach the addition of enzymes such as phytase to hydrolyze the same feed materials as claimed herein. The flavors are in amounts 0-5% (see claim 1). The rejection is being made under both statutes because the Office is not equipped to make prior art products and compare them with those of applicant's claims and so the burden is being shifted to applicant to show that these product claims are distinguishable over prior art. Applicants' claim is written in product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not that

of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976). When the prior art discloses a product that reasonably appears to be either identical with or only slightly different than the product claimed in this product-by-process claim, the burden is on the applicant to present evidence from which the Examiner could reasonably conclude that the claimed product differs in kind from those of prior art. In re Brown, 459 F2d 531, 173 USPQ 685 (CCPA 1972); In re Fessman, 489 F2d 742, 180 USPQ 323 and 324 (CCPA 1974); In re Marosi, 710 F2d 799, 218 USPQ 195 (Fed Cir. 1983).

7. Applicant's arguments filed 11/8/02 have been fully considered but they are not persuasive.

Applicant has argued that WO 98/34498 does not teach phytase enzyme nor the acid to stabilize the mixture. Applicant states that the Office Action points out that there is no disclosure of an acid stabilization. This is incorrect.

The patent teaches phytase enzyme in the form of wheat bran for it was known in the art at the time the invention was made that wheat bran was used for its phytase activity. See Stone et al. that uses fish silage (instead of krill hydrolysate) and canola meal with wheat bran, expressly stating that the canola meal was dephosphorylated by phytase from the wheat bran (see abstract). Furthermore, EP 0321004 teaches the equivalence of phytase enzyme produced microbially and phytase produced by wheat bran. See page 3, lines 5-20. EP '004 teaches the temperature when the enzyme is applied to the cereal: 20-60°C and teaches that the phytase is active at the low pH of 4-5. At page 3,

lines 45-50, enzyme dosages, and a phytin degrading unit definition is also given. See "standard conditions" for phytase given as 40°C and pH=5.5.

Apart from the above patents/reference, Nielsen et al teach at col. 1, lines 53-55, col. 3, lines 40-65 that phytases are obtained from microorganisms, that they dephosphorylate cereals, *and* that the process is carried out at pH=4-7 and temperatures of 35-65°C. It is for this teaching alone that this reference was applied and this teaching was considered important. Applicant is reminded that this is a rejection under 35 U.S.C. 103 and not 35 U.S.C. 102.

Finally, WO 98/34498 teaches wet krill hydrolysate mixed with dry carrier in the form of vegetable protein shown on page 19, lines 1-7 as canola, corn , soy, etc. Note the cereals shown in Nielsen et al, also the same. WO'498 teaches using wheat bran, which inherently contains phytase, and teaches that formic acid stabilizes hydrolyzed marine protein. See pages 30-32. Stone et al. teach stabilizing their fish silage and canola meal mixture that has been hydrolyzed with acid. See page 518, second paragraph. Thus, not only would it have been obvious to substitute wheat bran used for its phytase, with phytase from microorganisms (EP '004) but also to stabilize with acid as Stone et al has done as also WO '498. One of ordinary skill in the art is held accountable not only for the specific teachings of references, but also for the inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811, (CCPA 1969).

Applicant's response to the rejection at paragraph 6 has been carefully considered but is deemed to be unconvincing. All the patents teach the dephosphorylated product. Claim 15 is written in product-by-process format and as such, it is the novelty of the instantly claimed product that need be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, 191 USPQ (CCPA 1976).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Examiner **C. Sayala** at **Group 1761,** telephone number (703)

308-3035. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661. The fax phone number for this Group is (703)305-7718.

C. Sayala
Primary Examiner
Group 1761.